Decision Summary

A. Definitions

For the purposes of this decision CLBP is defined as:

1. an episode of low back pain that has persisted for three months or longer; and

2. is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.

B. TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Social Security Act.

C. In order to support additional research on the use of TENS for CLBP, we will cover this item under section 1862(a)(1)(E) of the Social Security Act subject to all of the following conditions.

1. Coverage under this section C expires three years after the publication of this decision on the CMS website.
2. The beneficiary is enrolled in an approved clinical study meeting all of the requirements below. The study must address one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs when the impact of prior TENS use is appropriately accounted for in the study protocol.
   i. Does the use of TENS provide clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
   ii. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
   iii. Does the use of TENS impact the utilization of other medical treatments or services used in the medical management of CLBP?

These studies must be designed so that the patients in the control and comparison groups receive the same concurrent treatments and either sham (placebo) TENS or active TENS intervention.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors

   (http://www.icmje.org).
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

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Decision Memo

TO: Administrative File: (CAG #00429N)
FROM:

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Susan Miller, MD
Lead Medical Officer

SUBJECT: Final Decision Memorandum for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N)
DATE: June 8, 2012

I. Final Decision:

A. Definitions

For the purposes of this decision CLBP is defined as:

1. an episode of low back pain that has persisted for three months or longer; and

2. is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.

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These studies must be designed so that the patients in the control and comparison groups receive the same concurrent treatments and either sham (placebo) TENS or active TENS intervention.

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a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
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j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
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m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

II. Background

Low back pain (LBP) is a widespread complaint in the United States. It is the fifth most common complaint for which professional health care advice is sought [Rathmell 2008; Chou 2010]. Approximately 75-80% of individuals in the United States will experience an episode of LBP in their lifetime; there is a 5% annual incidence of the condition [Weinstein 2005]. It is estimated that greater than 17 million elderly individuals experience at least one episode of LBP in a year in the U.S. [Morone 2009].

In a minority of patients, a medical history, physical examination, and appropriate laboratory/imaging studies can identify causes such as cancer, infection, compression fractures and inflammatory arthropathies such as ankylosing spondylitis. However, there is no well-defined etiology of the pain in approximately 85% of individuals who present with LBP [Negrini 2010].

For most people, LBP is a short-lived condition whether or not treatment is provided, lasting less than 12 weeks for 80-90% of those who experience it. However, a small but significant proportion of individuals, approximately 10 – 20%, will experience a continuation of LBP with disabling symptoms [Rathmell 2008; Chou 2010].

Many authors define persistent LBP lasting greater than or equal to 12 weeks or 3 months to be chronic [Khadilkar 2005; Machado 2008; Poitras 2007; van Middelkoop 2011]. We also, for the purposes of this decision memorandum, define CLBP as LBP that has persisted at least three months. Proposed treatment regimens for CLBP include a range of interventions including physical therapy, behavioral therapy, TENS, drug therapy, and surgery. Examples of physical therapy treatments include exercise therapy, traction, and body biomechanics education. These treatments are meant to reduce pain, inflammation, and muscle spasm, as well as increase strength and range of motion, and improve functional status.

TENS involves the delivery of electric current to the skin through surface electrodes, primarily for the intended purpose of pain relief. TENS has been used as a therapy for musculoskeletal pain in many anatomic sites of the body; it has also been used to treat post-surgical pain, labor pain, primary dysmenorrhea, as well as the pain associated with a host of other medical conditions.

TENS units are usually small, portable battery operated devices that deliver electrical current to the skin through electrodes. They are usually administered by a therapist in a clinical setting, and then self-administered by the patient, once adequately instructed. Usually, several skilled therapy sessions are required to establish the optimal stimulation settings and sites of electrode placement for a patient.

In clinical practice, the electrical characteristics of TENS units are varied among the devices used and the clinicians who apply them [Knight 2008]. Two examples of commonly used approaches are a frequency greater than 50 Hz (i.e., conventional or traditional TENS) or a frequency of 1-10 Hz (low frequency or acupuncture-like TENS) [Sluka 2009]. Conventional TENS is usually perceived by a patient as a tingling sensation, while low frequency or acupuncture-like TENS is experienced as a burning, needling sensation [Knight 2008]. TENS devices can also be configured to deliver different types of output patterns for individual patients, including those that produce constant pulses, and those that provide repetitive trains or bursts of electrical pulses delivered in a limited time period, followed by a specified period of no current flow. Moreover, a TENS device may also be configured to produce a modulated output, so that one or several of the parameters of the electrical stimulation are cyclically changed during a single application of treatment [Sluka 2009].

A variant of TENS, also included in this review, is interferential current (IFC) therapy. This form of treatment applies two separate medium frequency (2000 – 4000 Hz) sinusoidal currents to the skin simultaneously. These two currents can then be superimposed upon each other, so that the resultant current is different from either of the initiating currents. The rationale behind the application of dual electric currents is based on the fact that the impedance (or resistance) of skin and subcutaneous tissue is inversely proportional to the frequency of stimulation. Therefore, there is less resistance to current at 3000 Hz than there is at 300 Hz. Proponents of IFC therapy state that the combined currents will pass more easily through the skin and reach deeper levels of tissues producing stronger physiologic effects, while at the same time causing less discomfort than would be required by other forms of TENS [Knight 2008; Sluka 2009].

There are several theories that have been hypothesized to support the clinical use of TENS for pain relief. Originally, the Melzack and Wall gate theory of pain was considered as the foundation of the mechanism of action for TENS. In this theory, a "gate" in the dorsal horn of the spinal cord has the capacity to inhibit transmission of nociceptive stimulation to the ascending tracts of the nervous system. By using TENS to activate the large diameter afferent nerves of the peripheral nervous system, it was believed that these devices could block the noxious painful sensations that were being felt by the patient [Walsh 2010]. However, as more research has accumulated, investigators now believe that TENS may produce pain relief by activating the supraspinal nervous system as well as the afferent nerves that affect the spine. These effects are proposed to occur at least in part, due to the modulation of the body's endogenous chemicals (e.g., endorphins, glutamate, etc.) that affect the perception of pain [DeSantana 2008(b); Sluka 2009]. Some also claim that the use of TENS causes a local dilatation of blood vessels in injured tissues [Noble 2000], that might mitigate nociceptive sensations.

For purposes of research conducted to determine the effectiveness of TENS, pain measurement tools usually incorporate the use of scales and questionnaires. Using these measures, improvement or worsening of pain symptomatology can be tracked over time. Among the tools commonly used to quantify pain are:

a. Number scales – Used to measure pain intensity, these scales consist of a range of numbers (e.g., 0 – 100) with descriptors providing general correlative indications (e.g., 0 = no pain; 100 = maximal pain). Subjects are asked to identify the number that best describes their pain.

- Visual analog scale (VAS) – A VAS is an unnumbered line, frequently 100 mm in length,with contrasting descriptors at either end. The descriptors could be for example, no pain/worst pain, sharp/dull, etc. The patient is asked to make a vertical mark at the point along the continuum that best represents their pain level. The investigator measures the distance of the patient's marking from the left side of the line; this measure denotes the pain score [Knight 2008].

Investigators have also attempted to measure the effects of pain reduction or worsening through the use of questionnaires that gather patient perceptions of their activity and disability status. Examples of such outcomes instruments include:

a. Oswestry disability index (ODI) – The ODI is used to determine those activities of daily living (e.g., standing, walking, lifting, sitting, and personal care) that are disturbed by the presence of low back pain. Each item is answered on the basis of pain being experienced "today." The ODI can be self-administered [Ostelo 2005].

b. Roland Morris Disability Questionnaire (RDQ) – The RDQ is a condition-specific health status measurement tool created to assess physical function in individuals with low back pain. Patients select from 24 items that describe their current activities/limitations (e.g., walking, standing, bending/kneeling, sleeping, etc.) due to their back pain "today." The RDQ can be self-administered [Ostelo 2005].

c. McGill Pain Questionnaire – This questionnaire is a self-administered tool. Patients draw the location of their pain on a body diagram and use the listed pain descriptors and pain scales to express the characteristics and magnitude of their discomfort [Knight 2008].

Additionally, indirect measures such as strength, range of motion and physical functioning may be used to determine the effectiveness of pain interventions.

III. History of Medicare Coverage

Current National Coverage Determinations (NCDs)

For the convenience of the reader, we note the Medicare National Coverage Determinations Manual has a number of NCDs addressing several uses of TENS in various settings including home use and supervised use outside the home.

- Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)
- Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)
- Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)
- Transcutaneous Electrical Nerve Stimulators (TENS) (280.13)

Current Request

CMS generated this request internally. We limited our review to CLBP as defined above. We specifically excluded certain well-defined diseases that may contribute to low back pain but which are not primarily low back syndromes. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom. Certain systemic diseases such as rheumatoid arthritis, multiple sclerosis, etc, manifest many debilitating symptoms of which low back pain is not the primary focus. We believe that the appropriate management of these types of diseases is guided by a systematic strategy aimed at the underlying causes. While TENS may infrequently be used adjunctively in managing the symptoms of these diseases, it is clearly not the primary therapeutic approach.

Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage, §1812 (Scope of Part A); §1832 (Scope of Part B) §1861(s) (Definition of Medical and Other Health Services). Transcutaneous electrical nerve stimulation is durable medical equipment (DME), as referenced in §1861(s)(6) of the Act. This may not be an exhaustive list of all benefit categories for TENS.

IV. Timeline of Recent Activities

September 13, 2011	CMS posts a tracking sheet and opens a National Coverage Determination (NCD). The initial 30-day public comment period begins.
October 13, 2011	Initial public comment period ended. CMS received a total of 359 comments.
March 13, 2012	CMS posts the proposed decision memorandum for 30 days of public comment.
April 12, 2012	The public comment period on the proposed decision memorandum closes with 275 comments received.

V. FDA Status

Because the TENS device was marketed prior to the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, its market approval was "grandfathered" rather than the result of satisfying the requirements of the PMA regime. We understand that TENS units are cleared under 510(k) for marketing, and that TENS for pain relief has never been PMA approved. Since TENS for pain relief has only been 510(k) cleared and not PMA approved, it has not been found to have a reasonable assurance of safety and effectiveness (the PMA standard); therefore it has not been found by FDA to be effective/have clinical benefit for pain relief.

VI. General Methodological Principles

In general, when making NCDs under §1862(a)(1)(A), CMS evaluates relevant clinical evidence to determine whether or not the evidence supports a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or improves the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for Medicare beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary under §1862(a)(1)(A) of the Act.

A detailed account of the methodological principles of study design that are used to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.

VII. Evidence

A. Introduction

This section provides a summary of the evidence we considered during our review. The evidence reviewed to date in this NCA includes the published medical literature on pertinent clinical trials of TENS for CLBP.

B. Discussion of Evidence Reviewed

1. Questions

In order to determine if TENS improves the health outcomes of Medicare beneficiaries with CLBP, we pose the following questions:

1. Does the use of TENS produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
2. Does the use of TENS produce a clinically meaningful improvement in function in Medicare beneficiaries with CLBP?
3. Does the use of TENS produce a clinically meaningful, improvement in any other health outcome in Medicare beneficiaries with CLBP?

If the answer to any of the questions above is affirmative, is the evidence sufficient to confidently identify the patient or device characteristics that predict improved health outcomes?

2. External Technology Assessment

An external technology assessment was not commissioned for this review.

3. Internal Technology Assessment

Systematic reviews are based on a comprehensive search of published studies to answer a clearly defined and specific set of clinical questions. A well-defined strategy or protocol (established before the results of the individual studies are known) guides this literature search. Thus, the process of identifying studies for potential inclusion and sources for finding such articles is explicitly documented at the start of the review. Finally, systematic reviews provide a detailed assessment of the studies included.

Literature search methods

We searched the PUBMED and EMBASE databases, the Cochrane Library, and the National Guidelines Clearinghouse up to August 2011. Search terms included 'TENS for chronic low back pain' and 'transcutaneous electrical nerve stimulation for chronic low back pain.' We identified those studies with and without randomized control trial (RCT) design, meta-analyses and systematic reviews. Of the references found, we read through the abstracts and titles to find those that met the criteria below. We also reviewed references submitted to us by commenters and performed a hand search of bibliographies to identify other pertinent articles.

For the purpose of this analysis, we reviewed clinical trials with the following inclusion criteria:

- Adults with chronic low back pain (with or without leg pain) present for 3 months or greater
- Studies with ten or more patients
- Trials with well-defined comparators
- Studies where participants used TENS over a period of at least 4 weeks
- All models, frequencies, and wave patterns of TENS applied superficially to the skin
  Studies including data on individuals who experienced less than 3 months of pain or reported outcomes after less than 4 weeks of TENS treatment were included if subgroup analyses were performed meeting the criteria as above.

We excluded studies that examined chronic low back pain in individuals with pain related to malignancy, neurodegenerative diseases (e.g. multiple sclerosis), and well-defined rheumatic disorders (except for osteoarthritis).

Systematic reviews and meta-analyses that had as their main objective, either in part or in whole, a comparison of TENS versus sham TENs and/or other therapies for patients with chronic low back pain from the year 2005 forward were also included in our review. Those that discussed the use of TENS in the treatment of combined musculoskeletal conditions or in combined acute/chronic LBP were excluded if subgroup analyses were not performed within our parameters of interest.

Based on the criteria noted above, CMS has found a limited number of studies (see Table 2 for articles excluded from review). The pertinent rationale for our inclusion/exclusion criteria is twofold:

(1) CMS did not in this NCA include all potential uses of TENS. Uses of TENS that fall outside the scope of analysis are not impacted by our review, and thus we excluded studies of LBP associated with neurodegenerative (e.g. multiple sclerosis) disease, malignancy, or well-defined rheumatic disorders (except osteoarthritis).

(2) Furthermore, while LBP complaints are common, studies indicate that about 80% of lower back pain resolves in approximately 6 weeks, leaving 10-20% of those individuals experiencing this complaint to have discomfort that is more long-lasting [Rathmell 2008 and Chou 2010]. CMS defines chronic low back pain (CLBP), for the purpose of this NCD, as pain that persists for 3 months or longer. Using this definition, we believe that individuals with CLBP can experience pain for years or even for a lifetime. Thus we focused on evidence that addressed use over a comparable time period.

Systematic Reviews and Meta-analyses

Dubinsky R, Miyasaki J. Assessment: Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2010;74:173-176.

This systematic review summarizes the evidence on the efficacy of TENS in the treatment of pain associated with neurologic disorders, including CLBP. The authors searched MEDLINE and the Cochrane Library for clinical trials of more than ten patients that compared TENS to placebo or to another therapy to treat low back pain of differing etiologies, including multiple sclerosis. The authors noted that there were varied definitions among the included clinical trials for meaningful reduction in pain. Five studies were evaluated.

The review concluded that there was conflicting evidence for the use of TENS in the treatment of CLBP and that TENS should be deemed ineffective for this purpose.

Khadilkar A, Milne S, ,Brosseau L, Robinson V, Saginur M, Shea B, Tugwell P, Wells G. Transcutaneous electrical nerve stimulation (TENS) for chronic low-back pain. *The Cochrane Database of Systematic Reviews*, 2005, Issue 3. Art. No.:CD003008. DOI: 10. 1002/14651858. CD003008. pub2.

The main objective of this systematic review was to determine the effectiveness of transcutaneous electrical nerve stimulation in the treatment of chronic low back pain. A secondary goal was to determine the most effective parameters to administer TENS. These parameters could include stimulation factors, sites of application, application techniques and duration of treatment. The authors searched MEDLINE from 1966 to April 2005; EMBASE, and the Physiotherapy Evidence Database (PEDro) up to April 2005; and the Cochrane Controlled Trials Register, Issue 1, 2005. The authors included randomized controlled trials of outpatients 18 years old and above, with a diagnosis of chronic (greater than 12 weeks), mechanical low back pain. Patients with signs and symptoms of sciatic pain or a previous history of back surgery were not excluded. However, patients with malignancy, infection, inflammatory disorder or neurological syndromes were specifically excluded. All standard models of TENS were included and sham TENS was considered an acceptable placebo. Studies in which patients were provided TENS treatment percutaneously with acupuncture needles were excluded.

Only 2 articles met the inclusion criteria of this review. The authors concluded that the evidence provided inconsistent support for the use of TENS as an isolated treatment modality in the treatment of CLBP.

Khadilkar A, Odebiyi DO, Brosseau L, Wells GA. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain . *Cochrane Database of Systematic Reviews*, 2008, Issue 4. Art. No.:CD003008. DOI: 10. 1002/14651858. CD003008. pub3.

The main objective of this systematic review was to determine whether transcutaneous electrical nerve stimulation is more effective for the treatment of chronic low back pain than placebo.

Initially the authors searched MEDLINE from 1966 to April 2005; EMBASE, and the Physiotherapy Evidence Database (PEDro) up to April 2005; and the Cochrane Controlled Trials Register, Issue 1, 2005 (see above). For this update, they searched MEDLINE, EMBASE and PEDro from 2004 to July 19, 2007. They also searched CINHAL from its initiation until July 19, 2007, and the Cochrane Controlled Trials Register, Issue 3, 2007. Additionally, the International Clinical Trials Registry was searched for ongoing trials. The authors included randomized controlled trials of subjects aged 18 and over in which more than five LBP patients per treatment group were present. CLBP was defined as persistent pain, lasting more than 12 weeks, located between the inferior gluteal fold and the costal margin. Studies with subjects experiencing pain from malignancy, infection, fracture, inflammatory disorder or neurological syndromes were excluded. Studies that included subjects with a previous history of back surgery or signs and symptoms of sciatica were not excluded; however these types of patients had to represent a minority of the study sample in order for the article to qualify for review. Studies that investigated LBP of less than 12 weeks duration or of middle/upper back pain were excluded from the review unless data were presented separately for the population of interest. All standard models of TENS were included in the review, but not articles in which percutaneous delivery of the electrical stimulation was performed. The placebo TENS device accepted was one in which generally the TENS device was modified so that no electric current passed to the skin through the electrodes. Furthermore, comparisons of TENS to other treatment modalities were not considered by the authors. The outcome measures of greatest interest consisted of pain, functional status, generic health status, patient satisfaction and side effects. Secondary outcome measures consisted of physical examination measurements, medication use and use of medical services.

The authors established values to define minimal clinically important differences in pain scores and functional outcomes. When statistical pooling of data was not possible, the authors defined a criterion for consistency of findings among the included studies.

The authors found four trials to meet their criteria for review. They concluded that these trials failed to consistently demonstrate that TENS relieves the symptoms and reduces the disability associated with CLBP.

Machado L, Kamper S, Herbert R, Maher C, McAuley J. Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. *Rheumatology*. 2009; 48:520-527.

The goal of this article was to perform a systematic review and meta-analysis of placebo controlled randomized trials investigating the effects of treatment upon nonspecific low back pain (NSLBP). The authors searched MEDLINE, EMBASE, CINAHL, PyschInfor, and the Cochrane Central Register of Controlled Trials from the earliest record to November 2006. The authors included randomized controlled trials comparing treatments for NSLBP against placebo. Only trials with continuous measures of pain were accepted for review. Studies in which participants demonstrated radicular syndrome, cauda equina syndrome, infection, neoplasm, fracture, inflammatory disease, pregnancy or spinal surgery in the past 12 months were excluded. Also excluded were studies of primary prevention as were trials in which the placebo was a contemporary treatment (e.g. an educational booklet). The authors used the definitions of the American College of Physicians and the American Pain Society to evaluate the magnitude of treatment effects: large > 20 points; moderate 10-20 points; and small < 10 points). A secondary analysis was performed to evaluate the efficacy of treatments in individuals with specific duration of symptoms. In this analysis, the authors combined those trials in which patients experienced pain for greater than 6 weeks, into their definition of CLBP.

Two trials, with a total of 57 patients, were found investigating the use of TENS for CLBP as defined by the authors. The authors concluded that there was a moderate effect favoring analgesic efficacy with TENS. However, they also noted that the confidence intervals around these estimates of pain relief were not narrow enough to rule out small effects.

McIntosh G, Hall H. Low back pain (chronic). *Clinical Evidence*. 2008; 10:1116.

This is a systematic review that studied the effects of various treatments for chronic low back pain, including non-drug treatments. The authors searched for English language journals of RCTs or systematic reviews that contained trials that were at least single blinded (unless impossible) and included more than 20 subjects (with at least 80% follow up). The search included BMJ Clinical Evidence in May 2007, MEDLINE (1966-May 2007), EMBASE (1980-May 2007), Psychlit (1984-May 2007), The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2007, Issue 2 and several websites (NHS Centre for Reviews and Dissemination, Health Technology Assessment, Turning Research into Practice, and NICE). The authors defined chronic low back pain as "pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica)," of at least twelve weeks duration. They included studies of people with chronic low back pain with no radiation of discomfort, or studies that included subjects both with and without radiation, if the proportion of people with radiation was less than 50 percent. They excluded studies in which the participants exhibited chronic low back pain with symptoms or signs that suggest a specific underlying condition (e.g. infection, tumor, osteoporosis, rheumatoid arthritis, fracture or inflammation), and studies where the subjects manifested only sciatica and/or pain due to herniated discs.

Two systematic reviews and one RCT were included in the review. The authors concluded that the decision to use TENS as an isolated treated for CLBP is poorly defined by the evidence.

Poitras S, Brosseau L. Evidence-informed management of chronic low back pain with transcutaneous electrical nerve stimulation, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy. *The Spine Journal*. 2008;8:226-233.

This review evaluates the efficacy of TENS and other modalities for the treatment of nonspecific or rheumatic chronic low back pain that has lasted longer than 12 weeks. The authors searched for French and English RCTs and controlled clinical trials in MEDLINE, EMBASE, Current Contents, CINAHL, and the Cochrane Controlled Trials Register up to August 2006. They also searched the registries of the Cochrane Field of Rehabilitation and Related Therapies and the Cochrane Musculoskeletal Group and the Physiotherapy Evidence Database. Generally, comparisons of two active treatments were excluded as were trials where the patient acted as his/her own control. Trials with subjects that received the placebo, were untreated, or received routine conventional therapeutic approaches were accepted as controls. If concurrent therapies were provided to both investigative and control groups, these trials were also accepted. To a limited extent, cross over trials were included, but only the data prior to the first crossing was analyzed. Studies with differing electrical parameters and treatment frequencies were accepted.

In summary, the authors concluded that most of the TENS studies were of poor methodological quality and that variations in TENS parameters and treatment session characteristics made comparisons difficult. The authors also concluded that TENS may have an impact on the reduction of pain in the immediate and short term, but does not appear to have an impact on perceived disability or long term pain.

van Middelkoop M. et. al. A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *European Spine Journal*. 2011;20:19-39.

The objective of this systematic review was to determine the effectiveness of various physical and rehabilitation interventions for CLBP. All standard modes of TENS were among the interventions studied. In the investigations included for review, TENS was compared against sham treatment, percutaneous electrical nerve stimulation/acupuncture, and other active treatments. Also conventional TENS was compared to biphasic new wave TENS. The authors searched the Cochrane reviews, MEDLINE, EMBASE, CINAHL, and PEDro up to December 2008 and included articles in English, Dutch, and German. They included RCTs of adults over 18 years of age, with non-specific chronic low back pain that persisted for 12 or more weeks and that evaluated at least one clinically relevant outcome measure (pain, functional status, perceived recovery, or return to work). The authors excluded RCTs where subjects demonstrated specific low back pain due to conditions such as vertebral spinal stenosis, ankylosing spondylitis, scoliosis, and coccydynia.

Comparing TENS to sham treatment, the authors concluded that no statistically significant difference on post-treatment pain intensity and disability was found. Further they noted that percutaneous electrical nerve stimulation/acupuncture is more effective than TENS for post treatment and short term pain relief. Between TENS and active treatments, they noted that studies demonstrated there was no statistically significant difference in pain intensity. Finally, one study found no statistically significant differences in the comparison of conventional TENS with biphasic new wave TENS in terms of pain intensity and disability. The authors noted that most of the evidence reviewed was of low quality or was at high risk of bias.

Single Study Investigations

We found six single study investigations that fit our inclusion criteria. Five were randomized controlled trials (RCTs) and one used a sequential allocation design. The details of these trials are presented in Table 1 and summarized below.

Deyo R, Walsh N, Martin D, Schoenfeld L, Ramamurthy S. A Controlled Trial of Transcutaneous Electrical Nerve Stimulation (TENS) and Exercise for Chronic Low Back Pain. *New England Journal of Medicine.* 1990(a);322(23):1627-1634.

The purpose of this study was to examine the efficacy of TENS and stretching exercises alone and in combination for the relief of low back pain. One hundred forty five subjects with CLBP (ages 18-70 years) were randomly assigned to one of 4 groups, including the use of TENS alone and sham TENS. Outcome measures included those related to pain ratings, functional status, physical performance and the use of medical services. Outcomes were recorded after two and four weeks of home therapy and then again two months after the TENS had been discontinued.

The authors concluded that for patients with CLBP, treatment with TENS was no more effective than treatment with a placebo and that TENS adds no apparent benefit to exercise alone.

Itoh K, Itoh S, Katsumi Y, Kitakoji H. A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat chronic non-specific low back pain. *Complementary Therapies in Clinical Practice.* 2009;15:22-25.

The goal of this study was to determine whether acupuncture, TENS, or a combination of acupuncture and TENS was more effective for the treatment of chronic, nonspecific LBP in older patients. A total of 32 patients, ages 60 and above, were randomly allocated to four groups: those treated with acupuncture, TENS, acupuncture and TENS and those in the control group. Each subject received a total of five treatments, provided once per week. Outcomes were measured by the use of a visual analog scale and the Roland – Morris Disability Questionnaire for ten weeks. The authors concluded that their study demonstrated the use of combined acupuncture and TENS to be effective in patients with CLBP as measured by the specified outcomes.

Jarzem P, Harvey E, Arcaro N, Kaczorowski J. Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain. *Journal of Musculoskeletal Pain*. 2005(a); 13(2): 3-9.

The goal of this research was to study the efficacy of TENS for the treatment of CLBP. Three hundred twenty four subjects with CLBP of at least 3 months duration and without leg symptoms were randomized into 4 treatment groups that included 3 different types of TENS and sham TENS. Follow up occurred after 2 and 4 weeks of treatment in the home. Outcome measures included those describing function, motion and depression. The authors concluded that TENS was no better than sham TENS for the treatment of CLBP without leg symptoms.

Kofotolis N, Vlachopoulos S, Kellis E. Sequentially allocated clinical trial of rhythmic stabilization exercises and TENS in women with chronic low back pain. *Clinical Rehabilitation*. 2008; 22:99-111.

The purpose of this trial was to investigate the effectiveness of rhythmic stabilization exercises, transcutaneous nerve stimulation and the combination of these therapies upon females (aged 34-46) with chronic low back pain. Ninety-two participants were sequentially allocated into four groups: those receiving rhythmic stabilization exercises; those receiving a combination of rhythmic stabilization exercise and TENS; those receiving only TENS treatments; and those receiving placebo TENS. Treatments and/or training were administered five times per week for four weeks. Outcome measures included data pertaining to functional disability, intensity of pain, as well as trunk range of motion and endurance. Outcomes were recorded after completion of the treatment/training program, and at four and eight weeks after. The authors concluded that combining rhythmic stabilization and TENS was more effective than TENS alone, but not as effective as rhythmic stabilization alone in treating their study population.

Shimoji K, Takahashi N, Nishio Y, Koyanagi M, Aida S. Pain Relief by Transcutaneous Electrical Nerve Stimulation With Bidirectional Modulated Sine Waves in Patients With Chronic Back Pain: A Randomized, Double-Blind, Sham-Controlled Study. *Neuromodulation: Technology at the Neural Interface*. 2007;10(1):42-51.

The objective of this study was to compare the effectiveness of TENS using bidirectional modulated sine waves (BMW), to sham TENS in those with CLBP. Outcomes measured were relief of pain and increase in straight leg raising measurements. Twenty one subjects were randomly assigned to two groups: massage plus sham TENS or massage plus TENS using BMWs. Treatments were provided twice weekly for five weeks. The authors stated that their data suggested that there were neither long term effects of TENS by BMW nor interactive effects between massage and TENS.

Yokoyama M, Sun X, Oku S, Taga N, Sato K, Mizobuchi S, Takahashi T, Morita K. Comparison of Percutaneous Electrical Nerve Stimulation with Transcutaneous Electrical Nerve Stimulation for Long-Term Pain Relief in Patients with Chronic Low Back Pain. *Anesthesia & Analgesia*. 2004; 98:1552-6.

The purpose of this study was to evaluate the effectiveness of percutaneous electrical nerve stimulation (PENS) treatment of chronic low back pain, using a TENS group as the control. Sixty subjects were randomly assigned to one of three groups: PENS treatment; PENS then TENS treatment; and TENS treatment. Each group was treated two times per week for eight weeks. Assessment of participants' peak pain levels, physical impairment and analgesic consumption was performed during treatment and one and two months after. The authors concluded that repeated PENS therapy was more effective than repeated TENS therapy in relieving chronic LBP.

4. MEDCAC

A Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting was not convened on this issue.

5. Evidence Based Guidelines

We searched the National Guideline Clearinghouse (www.guidelines.gov) and the Internet more generally for relevant guidelines.

Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

Dubinsky RM, Miyasaki J. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2010 Jan 12;74(2):173-6.

Major Recommendations
Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (I-IV) are provided at the end of the "Major Recommendations" field.
Recommendations
1. Transcutaneous electric nerve stimulation (TENS) is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (Level A, 2 Class I studies).
2. TENS should be considered for the treatment of painful diabetic neuropathy (Level B, 2 Class II studies).

Level A = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies).

This guideline was also published as is further reviewed in this memorandum.

European Guidelines for the Management of Chronic Non-specific Low Back Pain

Airaksinen O, Brox J, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, Mannion A, Reis S, Staal J, Ursin H, and Zanoli G. European Guidelines for the Management of Chronic Non-specific Low Back Pain. 2004. Available at www.backpaineurope.org

The writers found “strong evidence that TENS is not more effective than placebo or sham TENS in the treatment of chronic low back pain (Level A)”, therefore TENS was not recommended for the treatment of CLBP

For these guidelines Level A (Strong Evidence) was generally consistent with findings for which ≥75 percent of the studies (a systematic review of multiple high quality RCTs) showed a similar result. It should be noted that CLBP was defined in these guidelines as low back pain that lasted at least 12 weeks unless otherwise specified.

Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Low Back Pain

Albright J, Allman R, Bonfiglio R, Conill A, Dobkin B, Guccione A, Hasson S, Russo R, Shekelle P, Susman J, Brosseau L, Tugwell P, Wells G, Robinson V, Graham I, Shea B, McGowan J, Peterson J, Tousignant M, Poulin L, Corriveau H, Morin M, Pelland L, Laferriére, Casimiro L and Tremblay L. Guidelines on Selected Rehabilitation Interventions Philadelphia Panel Evidence-Based Clinical Practice for Low Back Pain. *Journal of the American Physical Therapy Association*. 2001;81:1641-1674.

The panel concluded that there was "good evidence (Level I) of no clinically important benefit on pain with TENS." The Panel went on to state their recommendation that there is "poor evidence to include or exclude TENS alone (grade C for pain and function) as an intervention for CLBP."

For these guidelines Level I is evidence from at least 1 properly randomized controlled trial (RCT) and Grade C is poor evidence regarding inclusion or exclusion of an intervention, but recommendations may be made on other grounds. CLBP was defined as low back pain that lasted for >12 weeks.

The American College of Physicians and the American Pain Society

Chou R, Qaseem A, Snow V, Casey D, Cross T, Shekelle P, and Owens D. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. *Annals of Internal Medicine*. 2007;147:478-491.

The authors developed clinical practice guidelines for the diagnosis and treatment of low back pain. In these guidelines, they state that "[t]ranscutaneous electrical nerve stimulation…ha[s] not been proven effective for chronic low back pain."

For these clinical practice guidelines (based on their analysis of systematic reviews), chronic low back pain is defined as back pain that is present for more than 3 months.

In the initial public comments, CMS received references to two guidelines that made recommendations on the use of TENS in the treatment of CLBP.

One of these guidelines was *The Practice Guidelines for Chronic Pain Management: An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine* published in April 2010. This guideline states that "TENS should be used as part of a multimodal approach to pain management for patients with chronic back pain and may be used for other pain conditions (e.g. neck and phantom limb pain)."

The other guideline was issued by *The National Institute for Health and Clinical Excellence (NICE)* in 2009 on *Low back pain: Early management of persistent non-specific low back pain.* The NICE low back pain guidelines recommendation was to "not offer transcutaneous electrical nerve simulation (TENS)." However, the NICE guidelines went on to explain that "(t)hese guidelines have failed to recommend TENS as a treatment, not because of evidence that it does not work, but because there is no evidence that it is effective. The guideline development group did not find any large well-conducted large randomised controlled studies. TENS research should:

•Establish the most effective stimulation parameters for effective use.
•Assess pain relief when using TENS, overall daily pain, medication usage and healthcare consulting as outcomes in addition to disability."

It should be noted that the duration of "chronic back pain" and "chronic low back pain" in the NICE management for low back pain guidelines and the chronic pain management guidelines developed by a collaboration of pain management and anesthesia specialty societies respectively, was not specifically defined as CLBP in a similar manner as done for the purposes of this NCD.

6. Professional Society Position Statements

We did not find professional society position statements on TENS for CLBP beyond the guidelines cited elsewhere in this decision.

7. Expert Opinion

Following the submission of initial public comments, members of the TENS academic and manufacturing community met with CMS to formally present the evidence referenced in their public comments. CMS met with Kathleen Sluka, PT PhD from the University of Iowa, a clinician and academician who has authored and co-authored clinical studies and textbooks on TENS, along with a few of her colleagues. CMS also met with TENS manufacturer RG Medical, representatives from the Neuroscience Device Alliance that represents the largest number of TENS manufacturers in the U.S., and with academician and TENS researcher Melissa Martinson MS PhD from the University of Minnesota. During these meetings CMS was provided an overview of the TENS technology and was presented with evidence from clinical studies referenced in their initial public comments on the use of TENS for the treatment of low back pain and posted on the CMS website. There was not any persuasive additional evidence provided to CMS during any of the described meetings.

8. Public Comments

As part of the NCD process, CMS uses initial public comments to obtain information regarding the topic under study. However, public comments that provide information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and have less evidentiary weight useful for making a coverage determination. Public comments that contain personally identifiable health information (PHI) are not published on our website. When possible, comments were posted on the CMS website with the PHI redacted. Comments primarily comprised of PHI were removed in their entirety. CMS takes into consideration all public comments and responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. These comments are available on the CMS website.

Public Comment on the Proposed Decision: 03/13/2012- 04/12/2012

Approximately two hundred seventy five commenters wrote to CMS in response to our proposed decision memorandum.

FDA Status

Comment
Several commenters have stated that CMS should not remove coverage for a device that the FDA has approved or cleared as safe and effective.

Response
We disagree with the premise of the commenters' position. Because the TENS device was marketed prior to the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, its market approval was "grandfathered" rather than the result of satisfying the requirements of the PMA regime. We understand that TENS units are cleared under 510(k) for marketing, and that TENS for pain relief has never been PMA approved. Since TENS for pain relief has only been 510(k) cleared and not PMA approved, it has not been found to have a reasonable assurance of safety and effectiveness (the PMA standard); therefore it has not been found by FDA to be effective/have clinical benefit for pain relief.

CED and Evidence Gaps

Comment
Some commenters stated that studies demonstrating the effectiveness of TENS should be required, but in the meantime, coverage of the device should be continued.

Response
Based on the evidence we reviewed we have determined that TENS is not reasonable and necessary for CLBP under 1862(a)(1)(A) of the Act. Neither the comments we received, nor the discussions that we have had with industry and investigators have provided us with the persuasive scientific evidence to reach a different conclusion. We had proposed CED under 1862(a)(1)(E) of the Act as a means to continue coverage under a different statutory authority that permits coverage for items and services used in certain research. We will continue to cover TENs for CLBP under the Medicare program but only under the conditions set forth in this final decision memorandum.

Comment
Several commenters stated that it is not appropriate to use CED to cover TENS for relief of CLBP.

Response
Because the available evidence is not sufficient to conclude that TENS is reasonable and necessary for CLBP under 1862(a)(1)(A), and recognizing the burden that CLBP places on our beneficiaries, we decided on CED under 1862(a)(1)(E). Despite public comments objecting to the application of CED to TENS for CLBP, we believe that continuing to make CED available provides the opportunity to support clinical studies that might lead to better management of CLBP.

Evidence Review Issues

Comment
Several commenters believed that our coverage determination was based only on the 2010 Report of the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology.

Response
While the AAN report was a factor in our decision to open a review of this topic, we conducted our own separate review. The extensive bibliography that was considered in this coverage determination is noted throughout the NCA and in the bibliography section. The record as a whole supports our decision to narrow the coverage of TENS.

Comment
One commenter stated that CMS incorrectly conducted a systematic review, instead of a meta-analysis for its NCA.

Response
We disagree. Meta-analysis is properly conducted only when the component studies are homogeneous. As detailed in Table 1, there is marked heterogeneity of the study designs, participant characteristics, and interventions applied in the TENS studies that fit our inclusion criteria. It is unclear to us how our questions regarding the clinical significance of TENS for CLBP can be answered by attempting to combine such divergent study characteristics (some of which introduce substantial bias into the investigation; see Table 3) into a single meta-analysis.

Comment
Several commenters expressed concern that the exclusion criteria used to conduct the literature search of this NCA were biased against research supporting TENS. Commenters specifically claimed that chronic musculoskeletal pain will respond to TENS regardless of its anatomic location and therefore studies that investigated multiple anatomic sites of musculoskeletal pain should have been included in our review of the literature. Commenters also claimed that it was inappropriate to exclude studies where the length of treatment was less than 4 weeks.

Response
We disagree. We did not find persuasive evidence to support the commenters' claims of TENS generalizability across anatomic locations. We in fact found that sham (placebo) TENS produces equivalent analgesia to active TENS. If the commenters' generalizability claims were to be accepted we would be led to conclude that TENS is not more beneficial than placebo for any uses related to musculoskeletal pain in any anatomic location.

Though the purported uses of TENS are broad, we decided to limit the scope of our review, and thus the scope of our decision to TENS for CLBP. We also recognized that the AAN 2010 guideline did not address all possible applications of TENS, and our tracking sheet announcing the opening of this review provided public notice of our focus on CLBP. Thus we believe that the public would not have expected a broader consideration of TENS in the context of this reconsideration.

We believe, and have stated historically in past decisions that an assessment of evidence on health outcomes includes the durability of those outcomes. Section VI General Methodological Principles of this and past decision memoranda include by reference an appended General Methodological Principles of Study Design, which includes the following paragraph. Underline is added here for the convenience of the reader.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. <u>In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.</u> Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

Thus we believe that a four week assessment period is both clinically appropriate and consistent with our historical precedent.

We reviewed the studies that commenters believed should have been included in our analysis, were it not for our exclusion criteria. None of these studies met the criteria for our review. Those that were not included are listed in Table 2.

Clinical Experience Issues

Comment
Several commenters stated a concern that Medicare will in the future eliminate coverage for other long standing treatments.

Response
We appreciate the commenters' concern. It is not the agency's intent to remove coverage for any clinically appropriate long standing treatment. However, we believe it is important to periodically review past coverage determinations because advances in medical research and periodic assessments of historical practice should lead to more informed clinical care. Long standing use of a medical treatment is unfortunately no guarantee that it is in fact clinically appropriate or necessary.

Comment
Several commenters have stated that removal of coverage of TENS for CLBP would be the equivalent to overruling or restricting the physician's decision making process and interferes with the doctor-patient relationship founded on the physician's uncompromising commitment to patient welfare. Commenters have also stated that this decision substitutes the government's judgment for that of the physician.

Response
While we have great respect for a physician's decisions concerning the most appropriate treatment for a given patient, the ordering of an item or service by a physician does not inherently make such item or service reasonable and necessary for Medicare payment, or medically appropriate. We believe the patient and his/her physician should explore all appropriate treatments. On the other hand, Congress has empowered the Secretary to make national coverage determinations and these policies help to improve the efficiency of the system that must process many millions of claims per year and help to ensure that similar claims are processed in a similar manner. We believe that our final decision, which permits coverage of TENS for CLBP in certain trials, is fully consistent with our authority under the Act. We must comply with the statutory requirement that covered items and services must be reasonable and necessary; and we want to ensure that Medicare beneficiaries receive care that is supported by clinical evidence. Health insurance programs, including Medicare, that develop policies based on clinical evidence routinely place conditions on coverage.

Comment
Some commenters have stated that in their professional experience, many, but not all, of their patients with CLBP have used TENS to improve function and to avoid or lessen their use of medications and surgical procedures.

Response
While we acknowledge that some individuals are sincerely conveying their personal experiences with TENS, we must point out that evidence from formal clinical studies is more persuasive to draw confident conclusions about the impact of medical technologies. As we state in the General Methodologic Principles in the Appendix to this decision memorandum, anecdotal reports are subject to biases and do not carry the evidentiary weight of methodologically appropriate clinical studies. Therefore, we believe that based on the totality of the evidence reviewed for this final decision, TENS should be noncovered for CLBP except when provided in clinical trials that meet the standards set forth in this decision.

Comment
Some commenters have stated that the evaluation period currently mandated by Medicare policies is sufficient to determine which beneficiaries will respond to the purported effects of TENS.

Response
We disagree. As we have noted above, reports of personal experience are unfortunately subject to bias. The evidence we reviewed points clearly to a placebo effect, with sham TENS producing superior or equivalent pain relief as active TENS. We do not believe the initial evaluation period will preclude a placebo effect.

Implementation Issues

Comment
Several commenters noted that patients in their clinics often see a therapist for one session of TENS evaluation and education. No follow up of the patient is performed.

Response
This matter is beyond the scope of this NCA. It is our expectation that all Medicare policies and regulations regarding the coverage of TENS are followed.

Comment
One commenter asked if the coverage of TENS from the effective date of this decision forward would depend on the diagnosis code accompanying the claim.

Response
Though codes are used in the claims processing system to implement NCDs, coverage of TENS is not a coding issue *per se*. The scope of this decision is limited to the diagnosis of CLBP. We expect that physicians and providers would code correctly to describe the beneficiary's medical condition on the claim form. For further information on coding for TENS, interested parties may contact the Durable Medical Equipment Medicare Administrative Contractor in their jurisdiction.

Cost Issues

Comment
Some commenters have stated that TENS is an inexpensive, low risk treatment for those who experience CLBP and therefore its coverage should be continued by Medicare.

Response
Cost information is not considered in this national coverage analysis. While we agree that the apparent patient risks are low, we do not believe that outweighs the direction of the evidence base considered as a whole – that TENS does not improve health outcomes and therefore should be noncovered.

Public comments may be viewed using the following link:
http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=256&ExpandComments=n&ver=5&NcaName=Transcutaneous+Electrical+Nerve+Stimulation+for+Chronic+Low+Back+Pain&bc=ACAAAAAAIAAA&

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1862(l) of the Act).

In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, section 1862(a)(1) of the Act states in part that, with limited exceptions, no payment may be made under part A or part B for any expenses incurred for items or services:

- Which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)) or
- In the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section. ((§1862(a)(1)(E)).

Section 1142 of the Social Security Act describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which diseases, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically.

Section 1862(a)(1)(E) allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate under section 1862(a)(1)(A), and where additional data gathered in the context of clinical setting would further clarify the impact of these items and services on the health of Medicare beneficiaries. CED, for example, allows CMS to determine that an item or service is only reasonable and necessary when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise. For the readers' convenience, the 2006 CED Guidance Document is available at http://www.cms.gov/determinationprocess/downloads/CED.pdf

As noted earlier, our review sought answers to the questions below. We have repeated them here for the convenience of the reader.

Analytic Questions:

In order to determine if TENS improves the clinically meaningful health outcomes of Medicare beneficiaries with CLBP (for purposes of this NCD, defined as LBP persisting for at least 3 months), we pose the following questions:

1. Does the use of TENS produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
2. Does the use of TENS produce a clinically meaningful improvement in function in Medicare beneficiaries with CLBP?
3. Does the use of TENS produce a clinically meaningful improvement in any other health outcome in Medicare beneficiaries with CLBP?

   If the answer to any of the questions above is affirmative, is the evidence sufficient to confidently identify the patient or device characteristics that predict improved health outcomes?

We evaluated the evidence related to these questions based on the results of the reviewed literature, the quality of the methodology used, and the overall generalizability of the studies to our beneficiary population.

§ 1862 (a)(1)(A) Analysis

Respectful of the historical Medicare coverage of the use of TENS for CLBP, we did not decide lightly to undertake this NCD reconsideration. The NCDs which pertain to the treatment of chronic pain were implemented in 1988 (see section 160.7.1 and 160.13 of the NCD Internet Only Manual (IOM)) and 1995 (see section 280.13 of the NCD IOM). These NCDs permitted Medicare coverage of the use of TENS for CLBP, but did not provide a national coverage analysis (NCA) that would describe the evidentiary basis of the decisions made. Nonetheless, it is both appropriate and responsible to periodically revisit coverage decisions and test their conclusions against the present day evidence base. Depending on the evolution of that evidence base over time, such testing could logically result in broader, narrower or unchanged coverage.

In 2010, the Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology [Dubinsky 2010] concluded that TENS was ineffective in the treatment of CLBP, based on its systematic review of the literature. Upon reading that analysis, CMS determined that it would be timely to reexamine the evidence surrounding the use of TENS to establish whether it is sufficient to warrant coverage of this modality for CLBP. The research articles considered for this NCA were published both prior to and after our previous NCD decisions were made, allowing us to review the evidence broadly to come to our decision. The literature we apply to our questions on the use of TENS for CLBP is extensive in volume but has many limitations that prevent us from drawing confident and generalizable conclusions of benefit. Studies where authors claimed benefit were hampered by methodologic limitations. Other studies essentially reported no benefit, and the Kofotolis [2008] article concluded that TENS was less beneficial than rhythmic stabilization.

CLBP for purposes of this NCD is LBP that persists for at least 3 months. We did not propose any limitation of TENS coverage for use in pain that persists for a shorter period. Many published studies of TENS were too brief in duration to address our need for evidence on chronic use, and were thus not informative for the questions before us. The exclusion of studies where CLBP participants used TENS over a period of less than 4 weeks thus limited the amount of published literature on this topic. Few articles specific to the topic of TENS treatment of CLBP describe a protocol where the TENS unit was used and patient data were gathered for at least 4 weeks. The six studies summarized in Table 1 met these criteria.

The evidence demonstrates that the use of TENS for CLBP as defined within the scope of this reconsideration does not produce a clinically meaningful improvement in any of the considered health outcomes as noted below. It is apparent that sham (placebo) TENS produces equivalent analgesia as active TENS.

Study Results

1. Does the use of TENS produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?

   As noted in Table 1, the lengths of treatment in the reviewed investigations ranged from 4 to 8 weeks. During that time, only in Yokoyama [2004], did the VAS score between pretreatment and the end of treatment decrease significantly with the use of TENS. Notable is the fact that there was no sham TENS in this clinical trial. This result is contrasted with results from the following studies:

   - In Deyo [1990(a)], there was no difference in outcomes noted between those receiving active TENS treatment and sham TENS.
   - In Itoh [2009], after 5 weeks of treatment, there were no significant changes in VAS scores as compared to pre- treatment in the TENS group.
   - In Kofotolis [2008], after 4 weeks of treatment, discomfort as measured by the Borg verbal pain rating did not demonstrate a significant difference between those who received TENS and sham TENS. Also, there was no difference between pre- and post-treatment measurements of back pain severity in those who received TENS and sham TENS.
   - In Shimoji [2007], one week after 5 weeks of treatment with massage plus TENS, or massage plus sham TENS, there was no significant difference in pain ratings between those individuals who received the active versus the sham TENS.

   Therefore we conclude that, based on the available evidence, TENS does not produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP, since a sham unit appears to provide equivalent analgesia.

2. Does the use of TENS produce a clinically meaningful, improvement in function in Medicare beneficiaries with CLBP?

In the presence of chronic pain, rarely is the complete eradication of discomfort a realistically achievable goal of treatment. Instead the aim of treatment is to make the pain more tolerable and, potentially, to increase function [Bloodworth 2000; Stanos 2007].

Because individuals differ in their perception and tolerance of pain, and other factors may contribute to a more global sense of suffering, the study of pain relief can be challenging. A patient may, for example, perceive and self-report improvement after placebo or sham treatment. The intensity or tolerability of pain may vary temporally, even over the course of a single day due to factors unrelated to the pain-inciting physical condition itself. To reduce biases that may lead to erroneous conclusions about cause and effect, CMS believes that in combination with pain reduction, more persuasive studies in this field should include measures that track objective measurable improvement from the use of TENS; improvements, for example, that reflect the enhancement of the performance of activities of daily living (ADLs) and instrumental activities of daily living (IADLs).

Some of the authors in our reviewed studies did attempt to correlate TENS usage with outcome measures that reflect such a positive improvement in the lives of their patients. The pertinent results are as follows:

- In Deyo [1990(a)], at the end of 4 weeks of treatment, there were no clinically important or statistically significant differences in the functional outcomes of those who received TENS versus sham TENS. Functional measures included the overall modified Sickness Impact Profile score (physical dimension and psychosocial dimension scores) and a self-assessed level of activity.
- In Itoh [2009], by the end of treatment, the TENS group reported lower Roland Morris Questionnaire (RMQ) scores than the control group, but these differences were not statistically different.
- In Jarzem [2005(a)], functional measure scores (McGill activity scale, McGill work scale and the RMQ) were no different between those who received TENS and sham TENS at the end of treatment.
- In Kofotolis [2008], the change in Oswestry Index scores between pre-treatment and the completion of treatment with TENS were not statistically significant. The scores were also no different from those gathered after treatment with sham TENS.
- In Yokoyama [2004], a physician assessed the patient's degree of impairment on a multiple choice form. There were no statistically significant differences in these scores as compared to baseline throughout the entire study for those treated with TENS.

Therefore we conclude that, based on the available evidence, TENS does not produce a clinically meaningful increase in function in Medicare beneficiaries with CLBP.

3. Does the use of TENS produce a clinically meaningful, improvement in any other health outcome in Medicare beneficiaries with CLBP?

Authors have attempted to expand the breadth of outcome measures beyond that of pain ratings and functional scales in order to capture other relevant aspects of chronic disease that may be improved by the use of TENS. These outcome measures include:

- Physiologic parameters such as strength, range of motion (ROM), endurance
- Decrease in medication usage
- Changes of mood or emotion
- Usage of medical services

Unfortunately we find no persuasive evidence to support these claimed benefits. CMS believes that, while interesting, outcome measures that document changes in isolated physiologic parameters alone, such as strength, ROM and endurance are not sufficient to determine if TENS has a clinically meaningful benefit. Though improvements in these parameters may coincide with benefit, they do not necessarily assess the patient's capacity to perform on a day-to-day basis within their chosen environments. Instead, we believe that functional outcomes provide a more accurate indication of the clinical significance of a TENS treatment.

We recognize that the achievement of comparable pain relief with reduced need for medication is also an important potential outcome. CMS believes that assessment of reduced medication usage would require rigorous methodology in order to determine if this is indeed a predictable and generalizable benefit of TENS for CLBP.

Similarly our commenters believe that decreased dependence on the health care system, and specifically the reduction in consumption of medical resources, may also be an indication of improved health outcomes in patients with chronic pain. CMS believes that when a patient's dependence on the medical system is reduced, it may provide more opportunities for the patient to pursue his or her chosen activities, and thereby increase the individual's overall independence and quality of life.

Three articles met our inclusion criteria and reported outcome measures that we believed to be meaningful in this context. They provided the following results:

- In Deyo [1990(a)], the use of medical services in all treatment groups was tracked. There were no reported statistically significant differences in this measure between the TENS versus the sham TENS groups at the end of treatment.
- In Jarzem [2005(a)], the authors used the Zung Depression Scale to measure depression in patient groups during the treatment period. Patients also kept diaries to determine frequency of medication usage and to track the use of ancillary care. The authors reported no difference in these measures between those subjects receiving any type of TENS and those receiving sham TENS.
- In Yokoyama [2004], patients receiving TENS demonstrated no statistically significant differences in dosages of non steroidal anti-inflammatory drugs (as measured by numbers of pills consumed) throughout treatment with TENS. (There was no mention of narcotic use in these patients).

Therefore we are unable to conclude, based on the available evidence, that the use of TENS produces a clinically meaningful, improvement in any of these health outcomes in Medicare beneficiaries with CLBP within the scope of this decision.

Guidelines

Taken as a whole, the published guidelines did not support TENS for CLBP.

Systematic Reviews and Meta-analyses

The five systematic reviews and single meta-analysis we summarized above are limited by the individual studies they included. Because these works included, and were thus influenced by, material beyond the scope of our review, their conclusions are less persuasive to the questions posed in our analysis.

Educational Materials

Other published educational materials describe TENS but do not include an actual discussion of evidence that would permit us to critically review the method used to reach their conclusions.

National Institute of Neurological Disorders and Stroke: [Retrieved January 3, 2011 from http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm]

"When back pain does not respond to more conventional approaches, patients may consider the following options:
***
"Transcutaneous electrical nerve stimulation (TENS) is administered by a battery-powered device that sends mild electric pulses along nerve fibers to block pain signals to the brain. Small electrodes placed on the skin at or near the site of pain generate nerve impulses that block incoming pain signals from the peripheral nerves. TENS may also help stimulate the brain's production of endorphins (chemicals that have pain-relieving properties)."

National Institute of Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse: Although transcutaneous electrical nerve stimulation (TENS) is recognized as a complementary or alternative treatment modality for CLBP, "studies have shown that TENS treatments are not always effective for reducing pain." [Retrieved January 3, 2011 from http://www.niams.nih.gov/Health_Info/Back_Pain/back_pain_ff.asp]

"•Transcutaneous electrical nerve stimulation (TENS). A small box over the painful area sends mild electrical pulses to nerves. Studies have shown that TENS treatments are not always effective for reducing pain."

Our review of the more methodologically robust individual clinical trials leads to a conclusion that active TENS is no better than sham TENS for improving patient health outcomes related to CLBP.

Methodologic Limitation of the Evidence

Study Duration

The research designs in the reviewed literature limit our ability to evaluate the impact of continuous use of TENS on health outcomes in the Medicare beneficiary population. Moreover the study designs did not allow us to evaluate possible dampening of patient response to TENS over time.

As we have historically stated in Appendix B and noted above in our response to comments, the durability of an outcome is relevant to a determination of benefit. Thus the assessment of an outcome over a suitable period of time is a reasonable application of historic methodologic criteria for the evaluation of evidence.

We believe that in order to demonstrate a clinically meaningful impact of TENS on CLBP, it is important to understand the temporal relationship of TENS use to its putative benefits. For example, does TENS application at a point in time produce a benefit compared to a pre-treatment baseline and does any benefit extend for some significant period of time after removal? Or, does TENS produce a benefit only during the period when it is applied and active? To use a drug analogy, does TENS display a therapeutic profile like an antibiotic course where sustained relief of the infection follows a defined period of treatment or is it more akin to an antihypertensive medication where ongoing use is required to maintain a benefit?

It is also important to understand whether the putative benefits of TENS are affected by the treatment setting. Specifically, are claimed improvements in health outcomes of TENS dependent on the physical therapy services that are furnished concomitantly? Or does the available evidence give us confidence that these claims are generalizable to unsupervised use in the home setting?

To the best of our knowledge, there is one study [Marchand 1993], (Table 2) that begins to address this issue. However, we find this study less persuasive in the context of our review for several reasons.

1. The study enrolled subjects who fall outside of the scope of this reconsideration; specifically it included subjects with specific rheumatologic diagnoses.

2. The study sizew as modest overall and the active treatment arm itself was small. Of the total 42 subjects, 16 were controls and received neither other active treatment nor TENS device treatment.

3.

During the period of active treatment, TENS, but not placebo TENS was reported to decrease pain intensity in a sustained manner. However, while the study was planned for two treatments per week for 10 weeks (20 treatments) data were only reported for the first 16 treatments. It is thus not clear whether the reported impact of TENS during the active treatment period itself was maintained for the last 2 weeks.

4.

The study setting for the active treatment was a laboratory rather than the subjects' homes.

5. Ultimately the same long term effect, months after the treatments ended, was reported in patients treated with active TENS and placebo TENS. The authors speculated that an increase in physical activity as a result of a decrease in pain may have produced this outcome, but physical activity was not systematically addressed in the report.

Other authors have tried to address the temporal relationship of TENS to its purported outcomes. Bjordal [2011] notes that there is a general consensus that the optimal benefit of TENS is achieved during stimulation. This author also states that the value of the results of TENS trials where treatment effects have been measured beyond the period of stimulation is questionable.

This is particularly pertinent in light of the expanding literature that suggests the effects of TENS may in some part, be mediated by endogenous opioids and other pain modulating substances in the body [Kalra 2001; Liebano 2011; Leonard 2011]. It is postulated by some [Leonard 2011; Liebano 2011; Sluka 2009; DeSantana 2008] that repeated application of TENS may produce tolerance to its analgesic effects because of the development of tolerance to the opioid effects of TENS. While to the best of our knowledge the phenomenon of TENS tolerance has not been studied specifically in individuals with CLBP, the potential lessening of efficacy of TENS when applied in repeated long term dosages is pertinent to this NCA. These observations may explain why in some clinical studies it has been noted that though patients may initially respond well to TENS in terms of pain relief, there can be a significant drop in efficacy over time [Tulgar 1991(b); Fishbain1996; Johnson 1991; Johnson 1992]. For example, in one study of individuals with a variety of chronic pain conditions [Johnson 1991], 32% of the patients reported a decline in TENS efficacy from the time the unit was issued (at least a 3 month duration). These statistics included 13.7% of the patients who reported no relief at all from these units by the end of the study, even though they had experienced a "successful" trial session.

Study Bias

CMS notes potential for significant bias that limits our confidence in the reported results of this body of literature. Important methodologic limitations were present in the reviewed literature that could have affected reported outcomes (Table 3). For example, several of the studies did not provide a sham TENS device. These studies compared TENS devices to other exercise treatments and modalities as noted in Table 1. We believe that a sham TENS control is important to minimize the bias of a placebo effect.

Sham devices do not completely guarantee appropriate blinding of the patient or assessor. Patients in a clinic may talk among themselves and determine who has a working device. Furthermore, in the particular case of TENS, subjects with sham TENS must be educated so that those who do not feel the sensation of the working device are just as likely to have a positive response to the therapy as those who do perceive the TENS sensation. However, those previously familiar with a TENS or other devices providing electrical stimulation may be harder to persuade, and their pain/functional status may be influenced by their recognition of the true or sham device. Therefore, in order to attempt to determine whether patient blinding in a device study was actually successful, CMS believes an evaluation should be made at the end of treatment to determine subject thoughts as to that treatment they received (active versus sham TENS) and compare their response to the actual treatment. Only Deyo [1990(a)] fulfilled this research step (Table 3).

Furthermore, randomization does not entirely eliminate the possibility that the various arms of the study will differ by factors that potentially affect the outcome of the study. Known prognostic factors should be identified and analyzed to determine if by chance or by design flaw, differences are found between the baseline characteristics of the study and control populations. Though the authors of the above trials compared the characteristics of the study and control groups to determine similarity between the two, the comparisons varied widely. For example, in Itoh [2009], it was stated that, "No significant difference was found in baseline variables including age, disease, pain duration and VAS among the four groups." No table of baseline characteristics nor levels of statistical significance were supplied to support that statement. In Jarzem [2005(a)], it was stated that the four treatment groups were not significantly different in the categories of …"job enjoyment, stress level, heavy laborers, use of vibrating equipment, smoking history, weight loss, back surgery, medication needs or compensation claims in the past." Again, no table of baseline characteristics nor levels of statistical significance were provided to support the statement, but the demographic comparison was more detailed than that of the former study and more likely in our opinion to control for potential confounders that would affect the prognosis of the study subjects and thus the outcome of the study.

Additionally, in a device study it is important to document the case volume, expertise and other pertinent qualifications of the treating clinicians. Both treatment and evaluation can be affected by differing levels of clinician qualifications and experience. Such differences may present a significant threat to the validity of the trial. There should also be a clear description of blinding of those who administer the interventions and/or record/conduct evaluations in a well performed study [Boutron 2008]. For the most part, the reviewed studies did not provide this information (Table 3).

From our evaluation of the above criteria, we conclude that the risk of bias is high in many of the trials we examined and therefore the overall strength of the reviewed evidence is low.

Intent to treat (ITT) analyses

Patients may drop out of a trial for a number of reasons, including untoward effects of the intervention (e.g., symptomatology of CLBP and/or response to treatment) [Akl 2009]. In TENS studies this could have lead to an over or underestimate of the intervention's impact. Most of the studies described the reasons for patient loss to follow up (LFU). However, none of the papers provided descriptions of the last known outcomes of the LFU patients and only one study included an analysis that took into account possible outcomes of LFU patients. CMS believes that all patients enrolled in a study should be accounted for, and using an intent to treat analysis helps to more accurately gauge the impact of an intervention. There are several methods by which to impute outcomes in those participants who have dropped out of a study. If, however, the outcomes measures for LFU patients cannot be included in the final analysis, then at least a detailed discussion of the implications of the missing data is necessary [Cochrane 2012].

Generalizability/applicability to use in the Medicare population

As we reviewed the literature we were struck by the heterogeneous mix of patient populations, electrical characteristics of the devices studied, comparators used and outcomes measured (Table 1). These variable characteristics posed additional obstacles to assessing whether or not TENS therapy improves health outcomes in individuals with CLBP. It also hampers our ability to predict those factors that might determine the characteristics of patients who would have the most favorable outcomes with the usage of TENS.

Furthermore, when extrapolating evidence from a clinical trial to a clinical setting, CMS believes it is important to establish that the evidence gathered is relevant to our beneficiary population and the setting in which those individuals are treated. We note that Medicare claims data as illustrated below, demonstrate that of all the individuals who purchased new TENS units, approximately one-third are obtained by individuals below the age of 65, and two-thirds are obtained by individuals above the age of 65. We believe that the studies included in our evidence base reasonably attempted to represent these population groups.

However, as noted above, TENS use is directed towards the home setting once the patient has been educated in the workings of the device. But we note that the home was the main setting of TENS application in only two studies (Table 1). We do not believe that the results of treatment that occurs in a clinical setting under the hands-on care of a qualified therapist would necessarily be representative of the treatment result when TENS is self administered in a home setting.

We also note that three of the studies included in this review originated from Japan [Itoh 2009; Shimoji 2007; Yokoyama 2004] and one was from Greece [Kofotolis 2008]. Differences in the cultural attitudes and experiences towards pain in individuals from other countries compared to individuals from the United States may influence the outcomes of the research [Davidhizar 2004; Johnson 1997]. Though this is not necessarily a fatal flaw of these studies, these differences may limit the generalizability of the conclusions from these trials to the Medicare population.

In summary, based on the additional evidence that has been published (see section VII) since the original decision, we do not believe that the updated evidence base supports the coverage of TENS in CLBP. We, therefore, determine noncoverage under section 1862(a)(1)(A) of the Act.

§1862(a)(1)(E) Analysis

CMS appreciates the significant burden of CLBP on the beneficiary population, which may lead to frustration on the part of patients, their treating practitioners and their caregivers. However, this frustration should not be the underlying reason for coverage of an item or service in circumstances where treatments are not known to be beneficial.

We had proposed national noncoverage under section 1862(a)(1)(A), and CED of TENS for CLBP under section 1862(a)(1)(E). However, some public commenters criticized our proposal to apply CED to support the closure of the significant evidence gaps we outlined in the proposed decision. As a foundation for CED, CMS has emphasized three factors relevant to the appropriateness of a CED coverage determination. The first is that the basic safety of the proposed item or service must be assured. In the case of TENS for the treatment of CLBP, adverse events are rare (see Table 1) and usually mild.

A second is the potential benefit of the item or service for Medicare beneficiaries. As noted above, TENS has been historically thought to relieve chronic pain but the current evidence base refutes this assertion when applied to TENS for CLBP. We have not included other proposed uses of TENS with the scope of this review, and are not commenting on them here. If some use of TENS for CLBP can ultimately demonstrate improved health outcomes under conditions that can be generalized to the settings where TENS is delivered to beneficiaries, we would be interested in covering TENS when those conditions are fulfilled.

The third speaks to the challenges of conducting adequate trials. Bennett [2011] and Bjordal [2011] note that while conventional sources of bias do confound the TENS literature (e.g. lack of blinding; incomplete accounting for study drop outs/withdrawals, etc.), the characteristic of 'low implementation fidelity' may also account for the inconclusive findings in this body of literature. As various authors explain, low implementation fidelity of a study suggests that it contains sources of bias that may lead to an underestimation of treatment effect. Bennett [2011] details various examples of low fidelity in previously conducted TENS trials such as:

- the lack of information provided to patients concerning the sensations they may experience with the TENS device
- the lack of instruction received by patients concerning how to adequately self-administer TENS
- the lack of assessment of compliance in TENS trials
- the lack of reporting of concurrent use of pain medications and comparable assessment of analgesia between study groups
- the inadequacy of reporting of the pattern and duration of TENS use
- the adequacy of the TENS intervention itself (including electrical parameters, treatment duration/frequency, electrode placement, etc).

CMS acknowledges the difficulties that have plagued the development of an informative TENS evidence base and believes that an opportunity should be afforded to address the limitations of previous studies. We believe that CED can support the design and conduct of clinical studies to address these limitations.

In summary, we believe TENS for CLBP is an appropriate application of CED. Specifically, we believe that CED is needed to identify under what conditions, if any, the following questions might be answered affirmatively:

1. Does the use of TENS provide a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
2. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
3. Does the use of TENS impact the utilization of other medical treatments or services used in the medical management of CLBP?

We believe that systematic, protocol-driven data are important to increase the likelihood that beneficiaries can receive care in a manner to best achieve improved health outcomes. Care provided under these protocols generally involves greater attention to appropriate patient evaluation and selection, as well as the appropriate application of the technology. These additional protocol-driven data may alter the course of patient treatment based on the best available evidence, and may lead a physician to reconsider the use of the item or service or otherwise alter a patient's management plan, potentially improving health outcomes.

We expect that an approved clinical study that evaluates the health outcomes of the use of TENS under CED would have at least the following characteristics:

- The trial exhibits a randomized placebo controlled design.
- The outcomes are pre-specified in the protocol and speak to clinically meaningful improvements for beneficiaries.
- The method of the TENS application is standardized and designed to assess durable benefit.
- There is a detailed protocol driven description and confirmation of the TENS application, including type of TENS, electrical parameters being used, frequency and duration of device usage and account of electrode placement.
- The control group receives sham (placebo) TENS.
- Both the active and sham TENS groups receive the same appropriate usual care.
- The analysis follows an intent-to-treat principle.
- Missing data are accounted for in a methodologically appropriate manner.
- The study outcomes are specific and appropriate to the individual setting (e.g. home, therapy clinic, etc).
- The study is adequately blinded.
- Other therapies (including medications, physical therapy, etc.) for CLBP are controlled for in the study.
- Outcomes related to other medical services and treatments for CLBP are tracked (e.g. reduction or elimination of opioids/NSAIDs, clinically supervised therapies, interventional procedures, etc).
- The exclusion criteria are appropriate and not unjustifiably restrictive.
- The sample size is adequate to detect an appropriate effect size based on pre-specified meaningful outcomes.
- The enrolled subjects are representative of the relevant Medicare population. This means that the sample would, at minimum, reflect Medicare-relevant age and gender distributions, that are shown in the tables below:

Age distribution of Medicare beneficiaries purchasing a new TENS unit, 2006-2010

	Year				
	2006	**2007**	**2008**	**2009**	**2010**
Under 25	59	86	69	121	112
25 - 34	721	1,158	1,246	1,418	1,676
35 - 44	2,659	4,410	4,628	4,712	5,383
45 - 54	5,060	8,394	9,103	9,715	11,354
55 - 64	5,275	8,793	9,491	9,981	11,977
65 - 74	15,327	23,578	25,082	27,824	31,394
75 - 84	9,328	14,569	14,695	15,793	17,922
85 - 94	2,084	3,402	3,641	4,073	4,710
95 and older	66	108	124	168	177

	Year				
	2006	**2007**	**2008**	**2009**	**2010**
Total	40,579	64,498	68,079	73,805	84,705

Reason for eligibility of Medicare beneficiaries purchasing a new TENS, 2006-2010

	Year				
	2006	**2007**	**2008**	**2009**	**2010**
Aged without ESRD	26,714	41,564	43,435	47,683	54,026
Aged with ESRD	136	181	227	280	298
Disabled no ESRD	13,581	22,471	24,112	25,453	29,880
Disabled with ESRD	98	205	211	247	329
ESRD only	50	77	94	142	172
Total	40,579	64,498	68,079	73,805	84,705

Gender of Medicare beneficiaries purchasing a new TENS, 2006-2010

	Year				
	2006	**2007**	**2008**	**2009**	**2010**
Male	12,154	19,415	20,639	23,000	26,684
Female	28,425	45,083	47,440	50,804	58,020
Total	40,579	64,498	68,079	73,804	84,704

Source: Part B Medicare claims files

Duration of CED coverage for TENS

We have determined that three years is an appropriate duration for CED coverage for TENS. TENS itself is a relatively simple and inexpensive technology with low risk for adverse events. CLBP is a common outpatient complaint which suggests that potential subjects are readily available. Therefore we believe that approvable TENS studies could be developed, enrolled and completed within two years. That would give stakeholders the opportunity to submit a request for reconsideration of this NCD well before the expiration of CED based coverage. If the evidence base at that time supports conclusions other than those we have articulated in this decision, we could publish a final reconsideration before the expiration of CED.

Disparities

Studies performed in the United States should also provide evidence about benefits or harms related to other population classifiers that have been associated historically with healthcare access or outcome disparities, such as gender, age, sexual orientation and religion, and encourages additional studies in which such associations might be studied. We find it helpful when clinical studies include data on racial and ethnic factors where they are relevant to the conclusions that may be drawn about the impact of the investigational item or service.

CMS continues to support the development of relevant new evidence and we encourage stakeholders to talk with CMS if they are interested in conducting a clinical study.

IX. Conclusion

A. Definitions

For the purposes of this decision CLBP is defined as:

1. an episode of low back pain that has persisted for three months or longer; and

2. is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.

B. TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Social Security Act.

C. In order to support additional research on the use of TENS for CLBP, we will cover this item under section 1862(a)(1)(E) of the Social Security Act subject to all of the following conditions.

1. Coverage under this section C expires three years after the publication of this decision on the CMS website.
2. The beneficiary is enrolled in an approved clinical study meeting all of the requirements below. The study must address one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs when the impact of prior TENS use is appropriately accounted for in the study protocol.
   i. Does the use of TENS provide clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
   ii. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
   iii. Does the use of TENS impact the utilization of other medical treatments or services used in the medical management of CLBP?

These studies must be designed so that the patients in the control and comparison groups receive the same concurrent treatments and either sham (placebo) TENS or active TENS intervention.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors

(http://www.icmje.org).
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

APPENDIX A

TABLE 1: TENS Evidence Tables

Study: Deyo 1990(a)

Study Design	Random block assignment to one of 4 groups Assignments drawn from sealed envelopes and determined by a table of random numbers Subject and evaluator blinded to TENS/sham TENS Setting for interventions was predominantly the home Compliance checked for at home regimens At completion of 4 weeks treatment, data analyzed for 125/145 subjects (14% drop out rate)
Characteristics of Participants	Ages 18-70 years Inclusion criteria: LBP of at least 3 months duration Exclusion criteria: history of cancer; requiring corticosteroids or anticoagulants; maximal pain above T-12; use of a cardiac pacemaker; known heart disease; severe co-existing condition; previously unevaluated neurological deficit; inability to return for appointments; inaccessible by telephone; inability to speak English; individuals seeking/receiving disability compensation; previous use of TENS

Intervention	*Treatment groups:* TENS alone, TENS + exercise, exercise with sham TENS , sham TENS alone (TENS/sham TENS units were identical) *Concurrent therapy* Twice per week, all subjects received moist heat therapies, adjustments in electrode placement, and written/oral advice in body mechanics in a clinic environment Recommended that electric heating pads (loaned to all participants) be used twice daily at home Other treatments (medications, physical therapy, other health care providers) were not proscribed *Electrical parameters of treatment:* Patients in the TENS group received conventional high frequency TENS for 2 weeks (80 – 100 pulses per second, amplitude = 30), then experienced acupuncture –like TENS (2-4 pulses per second, amplitude = 100). Patients self selected preferred mode of TENS for 2nd two weeks of study. Modulated pulse rate mode used for all TENS *Electrode placement:* Four carbon impregnated electrodes (5.5 cm diameter) initially placed over area of most severe pain; moved as necessary to optimize pain relief For participants with radiating pain, electrodes placed on leg and back *Frequency/duration of treatment sessions:* All subjects receiving TENS/sham TENS received instructions for home use, at least 45 minutes, 3 times per day Exercise participants received a uniform set of 12 exercises to be performed daily In addition to daily home treatment assignments, patients were seen at medical facility 2 times per week for hot packs, adjustment of electrode placement, body mechanics advice.
Outcome Measures	Modified Sickness Impact Profile Self assessment of change of activity level (increased; decreased; unchanged) Pain overall improvement rating (6 point ordinal pain scale;1 = entirely gone; 6 = much worse) 10 cm visual analogue pain scale 10 cm visual analogue scale of improvement (0-100%) Ordinal scale of pain frequency (1 = never; 5 = all the time) Straight leg raising ability Spinal and hip flexion as measured by distance of fingertips to floor on maximal forward flexion Schober's test Use of medical services Success of blinding
Timeline of Treatment and Follow up	Treatments administered for 4 weeks Outcomes gathered at 2 and 4 weeks of treatment and 2 months after completion of intervention
Adverse events	Approximately one third of participants reported minor skin breakdown at the TENS electrode sites. One subject required the discontinuation of sham TENS due to severe dermatitis.
Results	The authors concluded that there were no clinically important or statistically significant differences in any outcome measuring pain, functional status, physical parameters or the use of medical services, at the end of 4 weeks of treatment between the participants using true versus sham TENS. Among the subjects receiving true TENS, 100% guessed that they received the functioning units. Of those receiving sham TENS 84% guessed that they received a functioning unit (but with a lesser degree of certainty).

Study: Itoh 2009

Study Design	Random block assignment to one of 4 groups Allocation table generated by Sample Size, version 2 Not a blinded study

	Setting for intervention was a medical institution Final data analyzed on 26/32 subjects (19% drop out rate)
Characteristics of Participants	Ages 61-81 years Lumbar or lumbosacral pain for six months or longer Inclusion criteria: no radiation of LBP, normal neurologic findings of lumbosacral nerves; not receiving acupuncture treatment for more than 6 months, Exclusion criteria: Major trauma or disease; receiving conflicting or on-going co-interventions Participants under drug regimens were included if there were no changes in medications or dosages for one month or longer
Intervention	*Treatment groups:* Acupuncture (ACP), TENS, acupuncture and TENS (A&T), control (CT) *Concurrent therapy:* No other co-interventions were being taken by participants during the study period(including analgesics, anti-inflammatory medications, or poultices containing methylsalicylic acid *Electrical and other parameters of treatment:* ACP: received treatment at selected acupoints; needles were inserted into the muscle for a depth of 10 mm using a 'sparrow specking technique' by trained and experienced acupuncturists; when the patient felt dull pain or obtained de qi, the needle manipulation was stopped and the needle was left in place for 10 minutes more TENS: single channel TENS unit producing a premixed amplitude modulated frequency (122 Hz) generated by 2 medium frequency sinusoidal waves of 4.0 and 4.122 kHz; TENS intensity adjusted to produce a tingling sensation 2-3 times the participant's sensory threshold ACP&T: treatments of ACP and TENS above were combined CT: use of topical poultice containing methylsalicylic acid as necessary *Electrode placement (TENS):* Two surface electrodes of differing sizes (ratio 1:7) used; smaller electrode placed at point of most tenderness and larger electrode placed the near side of the point *Frequency/duration of treatment sessions:* Once per week Each individual treatment of ACP or TENS was administered over a 15 minute session ACP + TENS was administered as 15 minutes of TENS, then 15 minutes of ACP
Outcome Measures	Pain intensity VAS (0-100 mm) Roland Morris Questionnaire (RDQ)
Timeline of Treatment and Follow up	All patients received specified treatment for 5 weeks Follow up was for 10 weeks after first treatment VAS measured immediately before 1st treatment and then again at 1,2,3,4,5, and 10 weeks later (before receiving treatment if indicated) RDQ measured immediately before 1st treatment and then again 5 and 10 weeks later (before receiving treatment if indicated)
Adverse events	One subject in A&T group dropped out secondary to deterioration of symptoms
Results	The authors reported that mean VAS and RDQ scores decreased in all groups during treatment. However during the 5 weeks of treatment the only statistically significant reduction in mean VAS between pre-treatment and week 5, was in the A&T group. At the same time point, the RDQ scores were lower in the ACP. TENS, and A&T groups as compared to the CT group. However, there was no significant difference in RDQ scores between the treatment groups.

Study: Jarzem 2005(a)

	Randomized into 4 groups by random number tables Patients were assigned to the group in consecutive fashion depending on the order of enrollment

Study Design	Physiologic data gathered by blinded observer; exercise program provided by blinded physiotherapist Setting for intervention was predominantly the home Compliance checked for at home regimens Final data analyzed for 324/350 subjects (7% dropout rate)
Characteristics of Participants	Ages between 18 – 70 Continuous LBP (without leg symptoms)for at least 3 months Inclusion criteria: Ability to come to required visits over the treatment period Exclusion criteria: Maximal pain above T12; previous use of TENS; seeking disability compensation; history of cancer, corticosteroid or anticoagulation use; sciatica; implanted pacemaker; concomitant physiotherapy or chiropractic therapy; surgery within past 3 months; major illness, pregnancy
Intervention	*Treatment groups:* Conventional TENS, acupuncture TENS, biphasic (nu-wave) TENS and sham TENS All groups provided with identical units. *Concurrent therapy:* All patients received an identical exercise program Reported that no patient had been chronically dependent on narcotics *Electrical and other parameters of treatment:* Unspecified except that original intensity was adjusted to the threshold point below noxious stimulation as per manufacturer recommendations (just below an intensity that resulted in muscle twitching) Patient could adjust intensity over course of study *Electrode placement (TENS):* Electrode placement optimized per manufacturer instructions and patient needs, then adjusted during study per patient preference *Frequency/duration of treatment sessions:* Daily/weekly treatment recommendation was unspecified Subjects used, on average, TENS units for "close to" 88 hours during the study; an average daily use of approximately 188 minutes
Outcome Measures	Roland disability scale McGill Functional Questionnaire (work and activity scales) Pain questionnaire used to gauge changes in pain patterns Zung depression scale Diary to record ancillary care, pain intensity as measured by a visual analogue score, medication usage, TENS usage, etc Hip and lumbar flexion Straight leg raising Isolift scoring
Timeline of Treatment and Follow up	Patients were taught to use TENS at home and then seen at 2 and 4 weeks for follow up.
Adverse Events	None reported
Results	The authors concluded that after one month, TENS was no better for the treatment of CLBP without sciatica than was placebo. It is noted that VAS were not analyzed secondary to incomplete data.

Study Design	Sequential allocation into one of 4 groups Single blinded Setting for interventions was a medical institution Final data analyzed for 88/92 subjects
Characteristics of Participants	Females, ages 34 – 46 years Failed a period of "rest" for 6 months and had received other forms of therapeutic treatment Inclusion criteria: complaint of low back pain (a) during and/or after activity and/or (b) during and/or after sitting and/or (c) during stair climbing Exclusion criteria: surgery, sciatica, radiographic abnormalities (i.e. spondylolysis, spondylolisthesis, lumbar scoliosis greater than 10 degrees), injuries of the trunk, muscle and tendon ruptures, previously exposed to rhythmic stabilization or TENS
Intervention	*Treatment groups:* Rhythmic stabilization; rhythmic stabilization and TENS; TENS alone; placebo stimulation *Concurrent Therapy:* No additional physiotherapy provided during treatment period *Electrical and other parameters of treatment:* Rhythmic stabilization exercises: 3 sets of 15 repetitions of alternating trunk flexion/extension isometric contractions at maximal resistance against resistance held for 10 sec provided by the same therapist (with prescribedrest sessions between each pattern and set) TENS: 40 – 45 minutes of TENS delivered in the prone position with a unit providing pulse duration of 200 µsec and frequency of 4Hz at a 'strong but comfortable' level of stimulation Rhythmic stabilization and TENS: subjects received 20 minutes of TENS , rest, then 20 minutes of rhythmic stabilization Placebo TENS – received at same site and for same duration as TENS group using identical units *Electrode Placement (TENS):* Four rubber electrodes (2 cm x 3 cm) placed on fascia thorocolumbalis and approximately 10 cm proximal, along midline of muscle (directly over site of pain) *Frequency/Duration of treatment sessions:* Participants were trained 5 times per week See above for specifics of each treatment program
Outcome Measures	Oswestry Low Back Pain Disability Questionnaire Borg verbal rating pain scale (0 = normal, 10 = emergency) Range of motion and endurance of trunk extension and flexion
Timeline of Treatment and Follow up	Baseline measures were obtained one week prior to training Follow up measures gathered at end of treatment program (4 weeks), then 4 and 8 weeks after
Adverse effects	None reported
Results	The authors concluded that short term rhythmic stabilization exercise is effective in the treatment of women with CLBP. Furthermore they stated that treatment with TENS appears to be more effective than treatment with placebo TENS, but less effective than a combination treatment of rhythmic stabilization and TENS. Finally the authors stated that TENS adds no apparent benefit to that of rhythmic stabilization alone.

Study: Shimoji 2006

Study Design	Random assignment of subjects to 2 groups Double blinded; specifically patients and operators of devices were blinded Settings for interventions was a medical institution Final data analyzed for 21/21 subjects
Characteristics of Participants	Group receiving sham TENS was 64±6 years; group receiving active TENS was 62± 3 years Group receiving sham TENS experienced CLBP for 2.8 ± 1.1 years; group receiving active TENS experienced CLBP for 2.5±0.9 years Exclusion criteria: Illnesses or pathologies that would provide a contraindication to electrotherapy such as peripheral vascular abnormalities, peripheral neuropathies, recent trauma and/or menstruation problems; subjects taking antihypertensive drugs or pain relief medications, or were likely to take pain relief medications; inability to attend appointments It was noted that the diagnoses of the participants were chronic lumbar strain, disc herniation , and spondylosis deformans, with or without osteoarthritis Subjects who had previously used TENS were allowed to participate in the study as long as they did not express definite beliefs about how TENS worked or whether different types of TENS had different treatment effects
Intervention	*Treatment groups:* Massage plus bidirectional modulated sine waves (BMW) TENS; massage plus sham TENS TENS/sham TENS provided by identical units *Concurrent Therapy:* TENS/sham TENS preceded by massage *Electrical and other parameters of treatment:* Bidirectional modulated sine wave device producing an amplitude modulated frequency of 122 Hz generated by 4000 -4122Hz wave forms Mean current amplitude was 17.8 ± 9.4 mA (range 4.5-23 mA) *Electrode Placement (TENS):* 2 carbon impregnated rubber electrodes (5.5x10 cm) applied to the skin of the back, approximately 10 cm apart from the spine, targeting spinal segments of afferent nerves emerging from the painful area *Frequency/Duration of treatment sessions:* Twotreatments per week (massage 15 minutes; TENS/sham TENS 15 minutes), with at least a 2 day interval between treatments
Outcome Measures	Numerical rating scale (NRS): 0 = "no pain", 10 = "worst pain" Straight leg raising
Timeline of Treatment and Follow up	Treatments were administered for 5 weeks with at least 2 day interval between treatment Post treatment NSR was collected in week 6 and compared to pretreatment measurement
Adverse Events	Adverse effects did not occur in those subjects receiving BMW TENS
Results	The authors noted that in their patient population, there was no significant difference in outcome measures after treatment with BMW or sham TENS. The authors also concluded that that there were no interactive effects between TENS and massage for treatment of LBP.

Study: Yokoyama 2004

Study Design	Random assignment into one of 3 groups No blinding of patients or physicians Setting for interventions was a medical institution Final data analyzed for 53/60 subjects
Characteristics of Participants	Ages: group receiving PENS: 60±12 years; group receiving PENS then TENS, 58±14 years; group receiving TENS, 59±13years LBP for more than 6 months Inclusion criteria: peak pain intensity of greater than 40 on a visual analog scale (see below); pain intensity had been maintained at stable level for at least 3 months prior to enrollment with non-steroidal anti-inflammatory drugs (NSAIDs) ; no experience with PENS; had received prior treatment with nerve blocks, physical therapy, and NSAIDs Exclusion criteria: pregnancy, osteomyelitis of the spine, discitis, tumor, ankylosing spondylitis, recent vertebral fracture, structural scoliosis, previous low back surgery
Intervention	*Treatment groups:* PENS, PENS and TENS, TENS *Concurrent Therapy:* Allowed to continue NSAIDs as desired Nerve blocks, physical therapy discontinued at time of study *Electrical and other parameters of treatment:* PENS therapy: 10, 32 gauge acupuncture like needles were placed 2 - 4 cm deep into the soft tissue/muscle of the low back according to the dermatomal distribution of pain; the needles were connected to bipolar leads from a low output generator (DC current); probes stimulated at 4/30 Hz; intensity of stimulus adjusted to produce the stimulus of the highest tolerable sensation without muscle contraction TENS therapy: Stimulation occurred at a frequency of 4/30 Hz *Electrode Placement (TENS):* Stimulation performed by 4 electrodes (2.5 cm) placed in standardized dermatomal pattern *Frequency/Duration of treatment sessions:* Twice weekly sessions TENS and PENS stimulation occurred for 20 minutes per session
Outcome Measures	Visual analog scale (0-100, with 0 = no pain; 100 = worst pain ever) ; peak pain on assessment day was rated Physician assessment of patient impairment: 0 = no impairment; 1 = mild, not affecting most activities; 2 = moderate, cannot perform some strenuous activities; 3 = limited, can only participate in light activities; 4 = severely limited NSAID consumption as determined by number of pills consumed
Timeline of Treatment and Follow up	Treatments provided for a total of 8 weeks (16 sessions) for those in the PENS and TENS group; subjects in PENS then TENS group received first 4 weeks of PENS, then 4 weeks of TENS Assessments made 2 weeks before the initial treatment, just before the initial treatment (baseline), 3 days after week 2, week 4, and week 8 treatments, then at 1 and 2 months after the sessions
Adverse Events	None reported
Results	The authors noted that in the group treated with TENS, a significant decrease in pain intensity occurred only at 8 weeks in comparison to baseline scores; there were no significant differences in physical impairment scores throughout study; there were no significant differences in dosages of NSAIDs as compared to baseline throughout study

TABLE 2: Characteristics of Excluded Studies, Systematic Reviews, Meta- analyses

Study	Reason for Exclusion*
Barker 2008	Duration of TENS treatment less than 4 weeks
Bertalanffy 2005	Study of acute low back pain
Bjordal 2003	Study of post – operative pain
Chabal 1998	Mixed sample of musculoskeletal conditions
Cheing 1999	Duration of TENS treatment less than 4 weeks
DeSanta 2008(a)	Review article
DeSanta 2008(b)	Review article
Facci 2011	Duration of TENS treatment less than 4 weeks
Fishbain 1996	Mixed sample of musculoskeletal conditions
Ghoname 1999	Duration of TENS treatment less than 4 weeks

Study	Reason for Exclusion*
Grant 1999	Imprecise location of back pain
Jarzem 2005(b)	Duration of TENS treatment less than 4 weeks
Johnson 2007	Mixed sample of musculoskeletal conditions
Kerns 2002	Review of pain in individuals with multiple sclerosis
Kerr 2003	Study evaluated acupuncture therapy versus non-functioning TENS comparator
Lehmann 1986	Inpatient treatment
Leonard 2010	Subjects were without disease
Leonard 2011	Mixed sample of musculoskeletal conditions
Lin 2010	Study evaluated electro-acupuncture, not TENS
Marchand 1993	Included individuals with rheumatic diseases (ankylosing spondylitis, rheumatoid arthritis)

Study	Reason for Exclusion*
Melzak 1983	Mixed sample of participants with acute and chronic LBP
Moore 1997	Duration of TENS treatment less than 4 weeks
Rakel 2003	Study of postoperative pain
Rakel 2010	Study confined to healthy subjects
Thompson 2008	Intervention consisted of transcutaneous spinal electroanalgesia, not TENS
Thorsteinsson 1977	Mixed sample of musculoskeletal conditions
Topuz 2004	Duration of TENS treatment less than 4 weeks
Tsukayama 2002	Duration of LBP may be less than 3 months
Tulgar 1991(a)	Duration of TENS treatment less than 4 weeks
Tulgar 1991(b)	Mixed sample of musculoskeletal conditions
Warke 2006	Study participants with diagnosis of multiple sclerosis

Study	Reason for Exclusion*
Yeung 2003	Study of electroacupuncture
Yip 2007	Mixed sample of musculoskeletal conditions
Zambito 2006	Duration of TENS treatment less than 4 weeks
Zambito 2007	Duration of TENS treatment less than 4 weeks

* Multiple reasons for exclusion may exist, but only one listed

TABLE 3: TENS- Bias

	Deyo 1990(a)	Itoh 2009	Jarzem 2005(a)	Kofotolis 2008	Shimoji 2007	Yokoyama 2004
1. Was there a sham TENS comparator to a TENS intervention?	Yes	No	Yes	Yes	Yes	No
2. Were patients blinded to the sham TENS, which would include being told that they may/may not perceive (nor need to) sensation from the device?	Yes	Not Applicable	Yes	Unknown	Yes	Not applicable
3. Was an assessment done to denote adequacy of patient blinding to active versus sham TENS?	Yes	Not Applicable	No	No	No	Not Applicable
4. Were the subjects in all relevant groups naïve to TENS?	Yes	Unknown	Yes	Yes	No	Unknown
5. Were the outcome assessors blinded?	Yes	Unknown	Physical measurements - yes	Unknown	Unknown	Unknown

	Deyo 1990(a)	Itoh 2009	Jarzem 2005(a)	Kofotolis 2008	Shimoji 2007	Yokoyama 2004
6. Were the qualifications and expertise of the clinicians who applied the interventions described?	No	ACP-yes TENS-no	No	No	No	No
7. Were the subjects receiving identical co-therapies (including pain medications)?	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
8. Were those seeking compensation/ disability or those presently on disability, excluded from the trial?	Yes	Unknown	Those seeking disability were excluded, but those on disability were not.	Unknown	Unknown	Unknown
9. Is the rationale for all drop outs specified?	No	Yes	Yes	Yes	Not applicable	Yes
10. Is the rationale for at least some drop outs associated with the symptoms related to CLBP and/or response to assigned treatment?	Yes	Yes	No	Yes	Not applicable	Yes

APPENDIX B

General Methodological Principles of Study Design

(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to that group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is to the extent that differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of that have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e. g. , using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in that confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to that the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix C

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